US Patent No. 6,743,430 **IDS PURSUANT TO MPEP §1134.01** 

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Submitter's Reference: 574313-5044

# Cama Dicant(s)

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Richard E. Parizek et al.

U.S. Serial No.

10/748,524

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**Assignee** 

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For

MULTICOMPONENT VACCINE CONTAINING

CLOSTRIDIAL AND NON-CLOSTRIDIAL

ORGANISMS IN A LOW DOSE

Examiner

Hines, JaNa A.

**Group Art Unit** 

1645

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## INFORMATION DISCLOSURE STATEMENT UNDER MPEP §1134.01

Commissioner for Patents P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Pursuant to MPEP §1134.01, the undersigned, on behalf of Merial Limited, a third party to the above-captioned patent application hereby calls the Examiner's attention to European Patent No. 0734731, which corresponds to the above-captioned application, the decision revoking European Patent No. 0734731, and the Notices of

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Opposition and documents cited therein with respect to European Patent No. 0734731, and more generally to the below-listed documents (submitted herewith as Exhibits and listed in the accompanying PTO 1449).

The decision revoking corresponding European Patent No. 0734731, it is respectfully believed, was not available sooner than September 19, 2007; and hence, is believed to have been first available later than two months after the publication of the above-captioned patent application. Likewise, the Notices of Opposition are not believed to have been available within two months of the publication of the above-captioned patent application. Thus, it is respectfully submitted that this Information Disclosure Statement (IDS) is timely under MPEP 1134.01 since documents cited herein and submitted herewith were not available within two months of publication of the above-captioned patent application.

Therefore, it is respectfully requested that the Examiner consider and make of record in the above-captioned patent application, the following, below-listed documents, with the US Patent and Trademark Office hereby authorized to charge any fee for this paper or its consideration and entry with the accompanying Exhibits, into the record of the above-captioned patent application, or credit any overpayment in such fees, to Deposit Account No. 50-0320 or 50-2354.

**Exhibit 1:** Decision Revoking the European Patent No. 0734731; September 19, 2007

**Exhibit 2:** Communication from European Patent Office; August 7, 2007

**Exhibit 3:** Communication of notice of Opposition on Application 96104209.0; February 20, 2007

**Exhibit 4:** Communication of a notice of opposition; January 19, 2007

Exhibit 5: Notice of Opposition on behalf of Novartis AG; January 4, 2007

**Exhibit 6:** Notice of Opposition on behalf of Merial Limited; January 3, 2007

Exhibit 7: Claims for European Patent Application; January 18, 2005

**Exhibit 8:** U.S. Patent 3,925,544

**Exhibit 9:** U.S. Patent 3,790,665

**Exhibit 10:** U.S. Patent 3,920,811

**Exhibit 11:** WO 94/22476

**Exhibit 12:** GB 2 050 830

**Exhibit 13:** GB 2 030 043

**Exhibit 14:** K.K. Kennedy et al., "Vaccination of Cattle and Sheep with a Combined *Clostridium perfringens* Types C and D Toxoid", Am J. Vet Res, vol. 38, no. 10, pages 1515-1517, October 1977

**Exhibit 15:** P.W. Wells et al., "Development of a combined clostridial and *Pasteurella haemolytica* vaccine for sheep", The Veterinary Record, pages 266-269, March 17, 1984

**Exhibit 16:** Animal Pharm, vol. 203, page 28, May 4, 1990

**Exhibit 17:** Clostridium Perfringens Types C & D Bacterin-Toxoid, Material Data Safety Sheet for Ultrabac CD, Pfizer Inc., pages 1-6

**Exhibit 18:** Clostridium Perfringens Types C & D Bacterin-Toxoid, Product Information for Utrabac CD, Pfizer

Exhibit 19: Animal Pharm, no. 124, page 19, February 27, 1987

Exhibit 20: Animal Pharm, no. 292, page 12, January 14, 1994

**Exhibit 21:** A.C. Webster et al., "Comparison of immune response stimulated in sheep, rabbits and guinea pigs by the administration of multi-component clostridial vaccines", Australian Veterinary Journal, vol. 62, no. 4, April 1985

**Exhibit 22:** Clostridial 7-Way Plus Somnumune, Compendium of Veterinary Products, 1993 Edition, page 294

**Exhibit 23:** J.R. Hepple, "Aluminium Hydroxide as an Adjuvant for Clostridial Vaccines", Internation Symposium on Adjuvants of Immunity, vol. 6, pages 173-180, 1966

**Exhibit 24:** Gerald L. Stokka, et al., "Inflammatory response to clostridial vaccines in feedlot cattle", JAVMA, vol. 204, no. 3, February 1, 1994

**Exhibit 25:** Sterne, "Immunisation of Sheep with Multi-component Clostridial", The Veterinary Record, vol. 74, no. 34, pages 909-913, August 25, 1962

Exhibit 26: "A Knotty Issue", Beef Today, page 22, September 1992

**Exhibit 27:** Dittmer, "Help in Injection Site Blemishes Arrives", CALF News Cattle Feed, September 1992

**Exhibit 28:** Smith, "Anti-clostridial product reduces carcass defects", FEEDSTUFFS, August 24, 1992

**Exhibit 29:** D.G. Eggleton et al., "Immunisation against ovine caseous lymphadenitis: correlation between *Corynebacterium pseudotuberculosis* toxoid content and protective efficacy in combined clostridial-corynecbacterial vaccines", Australian Veterinary Journal, vol. 68, no. 10, October 1991

**Exhibit 30:** D.G. Eggleton et al., "Immunisation against ovine caseous lymphadenitis: efficacy of monocomponent *Corynebacterium pseudotuberculosis* toxoid vaccine and combined closridial-corynebacterial vaccines", Australian Veterinary Journal, vol. 68, no. 10, October 1991

**Exhibit 31:** Flebbe et al., "Immunopotentiation by SGP and Quil A", Cellular Immunology, vol. 99, pages 128-139, 1986

**Exhibit 32:** G.J.A. Speijers et al., "Local Reactions of the Saponin Quil A and a Quil A Containing Iscom Measles Vacccine after Intramuscular Injection of Rats:

A Comparison with the Effect of DPT-Polio Vaccine", Fundamental and Applied

Toxicology, vol. 10, pages 425-430, 1988

**Exhibit 33:** B. Morein et al., "Iscom, a novel structure for antigenic presentation

of membrane proteins from enveloped viruses", NATURE, vol. 308, March 29,

1984

Exhibit 34: Vision Vaccines, MILES, Product Information for Vision 7 with Spur

Exhibit 35: Vision Vaccines, 1992, Press Release, page 1

**Exhibit 36:** Product Information on Vision, Intervet

**Exhibit 37:** 3,919,441

**Exhibit 38:** 4,292,307

Exhibit 39: Advertising Brochure "Alpha – 7" Just Once

Exhibit 40: Product Literature for Alpha-7, "Clostridium chauvoei – septicum –

novyi – sordellii – perfringens Types C & D Bacterin – Toxoid"

Exhibit 41: Product Literature for Alpha-7 from the Anchor Division of

Boehringer Ingelheim Animal Health, Inc.

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**Exhibit 42:** Product information for Alpha – 7, www.cattlenetwork.com

**Exhibit 43:** Information Disclosure Statement in respect of USSN 10/748,524 referring to Boehringer Ingelheim Animal Health, Inc. Distributor Policy and Terms [confirming public availability of Alpha – 7 in 1994]

**Exhibit 44:** Barharsefat et al., "Immunisation Active Des Bovins Par Le Vaccin Associe Antisepticemie Hemorragique (Pateurellose) Et Anticharbon Sympotatique (Qartiers Noirs) En Iran.", Arch. Inst. Razi, vol. 28, page 51-56, 1976

**Exhibit 45:** Noah, "Compendium of Data Sheets for Veterinary Products", Datapharm Publication Ltd., London, 1993-94

**Exhibit 46:** N.C. Srivastava, et al., "Preliminary Observations on Combined Vaccination Against Haemorrhagic Septicaemia and Black Quarter", Indian Vet., vol. 53, pages 168-174, March 1976

**Exhibit 47:** J.M. Blancou et al., "Etude d'un vaccine mixte contre le charbon bacteridien et le charbon symptomatique"Rev. Elev. Med. vet. Pays trop., vol. 27, no. 2, pages 183-187, 1974

**Exhibit 48:** M. Apley et al., "Subcutaneous Injection Site Comparison of Two Multiple Valent Clostridial Bacterin/Toxoids in Feedlot Cattle", AGRI-PRACTICE, vol. 15, no. 5, pages 9-12, May 1994

**Exhibit 49:** P.W. Wells, et al. "Development of a combined clostridial and *Pasteurella haemolytica* vaccine for sheep" The Veterinary Record, vol. 114, pages 266-269, 1984

**Exhibit 50:** "Clostridial vaccines vs. consumtion", Animal Health Update, Large Animal Veterinarian, page 20, January/February 1995

**Exhibit 51:** "IVS Annual", Vaccines and Antisera, 18(a) (i) Cattle, sheep and goats, Crows Nest, NSW: MIMS Publishing, page 405, 1994

**Exhibit 52:** P.D. Walker, "Bacterial vaccines: old and new, veterinary and medical", Vaccine, vol. 10, issue 14, pages 977-990, 1992

**Exhibit 53:** GB Application text as originally filed, "A multicomponent vaccine containing clostridial and non-clostridialorganisms in a low dose"

### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a true and complete copy of this INFORMATION DISCLOSURE STATEMENT UNDER MPEP §1134.01 and accompanying Exhibits 1-53 hereto is being served on the attorney of the patent owner at the address as provided for in 37 C.F.R. § 1.33(c), i.e., the attorney or agent of record, namely,

INTERVET INC.
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in accordance with 37 C.F.R. §§ 1.248(a)(4) and (b)(2), via first class mail, on November 7, 2007.

Respectfully submitted,

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